# EXHIBIT 156

**From:** Brantley, Eric
**Sent:** Tuesday, April 21, 2015 3:08 PM
**To:** Jones, Heather
**Subject:** Emailing: DEA-53013rev00, DEA-53014rev00, DEA-53015.01formRev01, DEA-53015.02formRev01, DEA-53015.03formRev00, DEA-53015.04formRev00, DEA-53015.05formRev00, DEA-53015rev00, DEA-53012rev00
**Attachments:** DEA-53013rev00.doc; DEA-53014rev00.doc; DEA-53015.01formRev01.docx; DEA-53015.02formRev01.docx; DEA-53015.03formRev00.docx; DEA-53015.04formRev00.docx; DEA-53015.05formRev00.docx; DEA-53015rev00.doc; DEA-53012rev00.doc

Heather,

Attached are the SOPs for Suspicious Order Monitoring

Thanks,

Eric

Your message is ready to be sent with the following file or link attachments:

DEA-53013rev00
DEA-53014rev00
DEA-53015.01formRev01
DEA-53015.02formRev01
DEA-53015.03formRev00
DEA-53015.04formRev00
DEA-53015.05formRev00
DEA-53015rev00
DEA-53012rev00

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

# STANDARD OPERATING PROCEDURE

| Qualitest an endo health solution | Title: **CUSTOMER DUE DILIGENCE VISITS** | |
|---|---|---|
| No.: **DEA-53013** | Version: **00** | Effective: **12/23/2013** |
| Department: **DEA COMPLIANCE** | | |

PURPOSE: The purpose of this SOP is to provide guidance for Qualitest employees and/or third party contractors investigating Qualitest primary and secondary customers for the potential risk of diversion of Controlled Substances and/or List 1 Chemicals.

SCOPE: This SOP applies to all Qualitest customers and secondary customers identified through chargeback data and/or other intelligence.

DEFINITIONS:

| | |
|---|---|
| Investigator | A person authorized by the Qualitest Director, DEA Compliance or Manager, Customer Due Diligence & SOM to conduct customer due diligence site visits. This includes Qualitest employees and third party contractors. |
| Suspicious Order | An order for a Controlled Substance or List 1 chemical which is of an unusual size, frequency, and/ or deviates substantially from a normal pattern. |
| Boundary | [redacted] |
| Controlled Substance | A drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V in Title 21 U.S.C. |
| List 1 Chemical | A chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of Title 21 U.S.C. and is important to the manufacture of the controlled substance. |

RESPONSIBILITY: The SOM team has the primary responsibility for compliance with this SOP.

SAFETY: N/A

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|---|---|---|
| No.: **DEA-53013** | Version: **00** | Effective: **12/23/2013** |
| Department: **DEA COMPLIANCE** | | |

REFERENCES: Identifying, Blocking and Reporting Suspicious Orders SOP

ATTACHMENTS: N/A

PROCEDURE:

I. Typical reasons for site visits

A. Customer due diligence site visits shall be considered under the following circumstances:

1. SOM team requests a visit when more information is needed in approving a new customer account request for Controlled Substances or List 1 Chemicals.
2. SOM team requests a visit based on analysis and/or investigation findings.
3. SOM Advisory Board requests a visit during monthly review of customers.
4. SOM team requests a visit when a customer requests to begin ordering Controlled Substances, List 1 Chemicals or is seeking a boundary increase.

II. Conducting Site Visits

A. Investigators must schedule and complete the site visit within a reasonable amount of time from the request.

B. The completed site visit report must be submitted within a reasonable period of time after the visit is concluded. The Director, DEA Compliance or Manager, Customer Due Diligence & SOM will determine a reasonable period of time based on factors such as the number of customers visited, and locations.

C. Investigations are scheduled with the owner or Pharmacist in Charge (PIC), and are conducted at the customer's DEA registered location.

D. All visits must be documented on the appropriate checklist based on the customer class of trade. All requested documentation will be collected; including dispensing records void of patient identifying information.

E. Reports must be submitted to the Director, DEA Compliance and Manager, Customer Due Diligence & SOM for review. The reports must be uploaded to the repository as part of the customer's file pursuant to the Record Retention Policy.

III. Investigation

A. The Investigator will be given all pertinent information about the customer prior to the visit.

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B. The investigator must document obvious signs of potential diversion including but not limited to:

1. Illicit drug use or transactions outside and around pharmacy
2. Long lines of people waiting at the pharmacy
3. Lack of a front end inventory
4. Significant number of out-of-state vehicles parked at pharmacy
5. FedEx or UPS shipping materials that could be evidence of internet activity

C. The actual numbers must be obtained from the customer (if unavailable the owner or PIC provides an estimate) when asking the following questions:

1. [redacted]
2.
3.
4.

D. The names and DEA numbers for [redacted] of all Controlled Substances as well as [redacted] must be obtained. Also obtain the name and DEA numbers for the [redacted] as directed by the SOM Team.

IV. Investigation Review

A. The Director, DEA Compliance or Manager, Customer Due Diligence & SOM will review the findings. The Investigator may be consulted during this process.

B. If it is determined that there is significant risk of potential diversion, action may be taken against the customer after review by the Advisory Board. This may include denial of the new customer's application for purchasing Controlled Substances or discontinuing the sale of Controlled Substances with an existing customer or blocking the customer from ordering Controlled Substances and List 1 Chemicals. Any customer that is dropped due to significant risk of diversion will be reported to DEA.

| Qualitest an endo health solution | Title: **CUSTOMER DUE DILIGENCE VISITS** | |
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C. Prompt notification is sent to the sales team, customer service and the customer by the Director DEA Compliance or the Manager, Customer Due Diligence & SOM.

D. Customers that have been blocked from ordering Controlled Substances and List 1 Chemicals may request to have their ability to order Controlled Substances and List 1 Chemicals reinstated. Consideration of reinstatement of the customer will be made after a reasonable period of time has passed and after the reasons for the block have been mitigated as established by the SOM Team. The SOM Advisory Board will review all pertinent information for account reinstatement during the next scheduled SOM Advisory Board meeting. A significant investigation and remediation detail must be provided before reinstating the customer's Controlled Substance ordering ability.

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END SOP

REVISION HISTORY:
REV00 – New SOP

# STANDARD OPERATING PROCEDURE

| Qualitest an endo health solution | Title: **IDENTIFYING, BLOCKING, AND REPORTING SUSPICIOUS ORDERS** | |
|---|---|---|
| No.: **DEA-53014** | Version: **00** | Effective: **12/23/2013** |
| Department: **DEA COMPLIANCE** | | |

PURPOSE: The purpose of this SOP is to provide guidance on identifying, blocking and reporting Suspicious Orders. It also provides guidance on reviewing, documenting, and resolving excessive or Suspicious Orders in order to comply with the requirements of the Controlled Substance Act and Part 21 of the CFR .

SCOPE: This procedure applies to all customers and all customer orders of Controlled Substances and/or List 1 Chemicals (as defined below), and all Qualitest personnel involved with the initiation, processing or review of customer orders for Controlled Substances and List 1 Chemicals.

DEFINITIONS:

| | |
|---|---|
| Suspicious Order | An order for a Controlled Substance or List 1 Chemical which is of an unusual size, frequency, and/or deviates substantially from a normal pattern. |
| Controlled Substance | A drug or other substance, or immediate precursor, included in schedule I, II, III, IV or V of Title 21 of U.S.C. |
| List 1 Chemical | A chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of Title 21 of U.S.C. and is important to the manufacture of the controlled substances. |
| Boundary | [redacted] |
| Order of Unusual Size | A Controlled Substance order that is significantly larger than the orders usually placed by the customer or by customers of the same size and class of trade. |
| Unusual Frequency | A Controlled Substance order that is placed significantly more frequent than orders normally placed by customer or customers the same size and class of trade. |

| Qualitest an endo health solution | Title: **IDENTIFYING, BLOCKING, AND REPORTING SUSPICIOUS ORDERS** | |
|---|---|---|
| No.: **DEA-53014** | Version: **00** | Effective: **12/23/2013** |
| Department: **DEA COMPLIANCE** | | |

| | |
|---|---|
| Unusual Pattern | A Controlled Substance order that is a significant deviation from customer's normal ordering pattern or the ordering pattern of customers of the same size and class of trade. |
| SOM Tool | An Information Technology program that uses an algorithm to identify suspicious orders. |

RESPONSIBILITY: The Qualitest SOM team is responsible for following this SOP

SAFETY: N/A

REFERENCES:
Qualitest SOP Due Diligence Investigations
Qualitest SOP Cage/Vault SOM

ATTACHMENTS: N/A

PROCEDURE:

I. Order Review

A. Every Controlled Substance held order must be reviewed by the SOM team to determine if it is a Suspicious Order as defined by 21CFR 1301.74(b) and this SOP. As necessary, the SOM team will contact customer service and/or the customer to obtain additional information regarding the order. Controlled Substance orders are deemed suspicious if they meet one or more of the below:

1. Order is of unusual size
2. Order is of unusual frequency
3. Order deviates substantially from normal pattern

B. Controlled Substance orders deemed suspicious must be reported to DEA by the Director, DEA Compliance or when appropriate, the Manager, Customer Due Diligence & SOM.

C. Suspicious Orders can be identified by:

1. SOM tool; or
2. Customer Boundary exceeded; or
3. Cage/Vault distribution center employee(s) or order entry employee(s) (Refer to cage/vault SOM SOP)

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| Department: **DEA COMPLIANCE** | | |

D. Controlled Substance orders of unusual size can either be the result of an order error or intentional orders placed by the customer. The SOM team must determine if the Controlled Substance order is an error or intentional order.

1. Order entry errors are NOT reported to DEA as suspicious orders and must not be shipped. These orders do not count against the customer's boundary, and the accrual is readjusted.
2. Intentional orders are evaluated using order history, experience and information provided by customer.
    a. The Controlled Substance order is released if justified
    b. The Controlled Substance order is blocked if not justified
    c. The Controlled Substance order is blocked and reported to DEA if not justified and suspicious.

E. Controlled Substance orders of unusual frequency are determined by the SOM tool or SOM team review.

1. Frequency is determined using order history.
    a. The Controlled Substance order is released if justified
    b. The Controlled Substance order is blocked if not justified
    c. The Controlled Substance order is blocked and reported to DEA if not justified and suspicious.

F. Controlled Substance orders that deviate substantially from the normal ordering pattern are determined by the SOM tool or SOM team review. Substantial deviations may include but are not limited to:

1. Orders for an unusually high percentage of a particular strength of a Controlled Substance.
2. Orders for an unusually high percentage of Controlled Substances compared to non- controlled substances.
3. Other deviations based on the knowledge and experience of SOM team.
    a. The Controlled Substance order is released if justified
    b. The Controlled Substance order is blocked if not justified
    c. The Controlled Substance order is blocked and reported to DEA if not justified and suspicious

II. Evaluation and Resolution of Held Controlled Substance Orders

| Qualitest an endo health solution | Title: **IDENTIFYING, BLOCKING, AND REPORTING SUSPICIOUS ORDERS** | |
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A. When the SOM team releases the held Controlled Substance order, the SOM team must ensure that the reasons for releasing the order and all supporting information have been documented and saved pursuant to the Record Retention Policy.

B. When the SOM team blocks a Controlled Substance order but does not deem the order Suspicious, the SOM team must ensure that the reasons and all supporting information have been documented and saved pursuant to the Record Retention Policy. The sales and/or customer service team will notify customer of all blocked Controlled Substance orders.

C. When the SOM team blocks a Controlled Substance order and deems it Suspicious, the SOM team must ensure the reasons and all supporting information have been documented and saved pursuant to the Record Retention Policy prior to submitting the order to Director, DEA Compliance or designee for reporting to DEA.

D. If the SOM team is unable to make a decision based on information available:

1. The Controlled Substance order is held as well as subsequent Controlled Substance orders until additional information is obtained and/or a site visit is completed pursuant to the Due Diligence Site Visit SOP.

E. Based on the findings of the site visit:

1. The Controlled Substance order is released and consideration is given to evaluating the customer's boundary
2. The Controlled Substance order is blocked and reported to DEA
3. Customer may be terminated from purchasing Controlled Substances
4. If a customer is reported to DEA as a suspicious customer, the customer will be terminated from purchasing Controlled Substances.

END SOP

REVISION HISTORY:
REV00 – New SOP

E0607.10

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| Qualitest an endo health solution | Title: **WHOLESALE DISTRIBUTOR/ CHAIN DISTRIBUTION CENTER QUESTIONNAIRE** | |
|---|---|---|
| Form No.: **DEA 53015.01** | Version: **01** | Effective: **07/15/2014** |
| Department: **DEA** | | |

## I. WHOLESALER/CHAIN CORPORATE HEADQUARTERS

1. Wholesaler Name: Click here to enter text.
2. DBA (if any): Click here to enter text.
3. Wholesaler Address: Click here to enter text.
4. Wholesaler Phone Number: Click here to enter text. Fax Number: Click here to enter text.
5. Wholesaler Email Address: Click here to enter text.
6. Name of Principle owner(s): Click here to enter text.
7. Ownership type (check one):
   ☐ Sole proprietor ☐ Corporation ☐ Other
8. Owner(s) Name: Click here to enter text.* If Corporation provide list of Officers
9. Owner Business Address: Click here to enter text.
10. Owner Phone Number: Click here to enter text. Fax Number: Click here to enter text.
11. Owner Email Address: Click here to enter text.
12. Has owner/officers ever had a DEA registration suspended or revoked? Yes ☐ No ☐
    a. If yes, provide details (attach documentation)
    _____
13. Has the owner/officers ever been convicted of a crime relating to distribution of controlled substances or listed chemicals ? Yes ☐ No ☐
    a. If yes, provide details _____ (please attach documentation)

## II. DEA REGISTERED DISTRIBUTION CENTER-- WHOLESALER/CHAIN

14. Wholesaler Name: Click here to enter text.
15. Facility Address: Click here to enter text.
16. Facility Phone: Click here to enter text.
17. DEA Registration # of Facility: Click here to enter text. (please attach copy).
18. State License # for Facility: Click here to enter text.(please attach copy).
19. State Controlled Substance license #: Click here to enter text.(please attach copy).

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## III. PRIOR HISTORY OF DISTRIBUTION CENTER

20. Has DEA registration of the facility ever been suspended or revoked? Yes ☐ No ☐
    a. If yes, provide details _____ (please attach documentation)
21. Has the Designated Representative/Person in Charge ever been convicted of a crime relating to distribution of controlled substances? Yes ☐ No ☐
    a. If yes, provide details _____ (please attach documentation)
22. Have there been any disciplinary actions taken against facility by any state? Yes ☐ No ☐
    a. If yes, provide details _____ (please attach documentation)
23. Is wholesaler VAWD certified? Yes ☐ No ☐ (please attach copy of certification)

## IV. BUSINESS INFORMATION

24. Please provide a general description of the business or the facility: Click here to enter text.

25. Customer categories which the facility(s) supply:

| | | | |
|---|---|---|---|
| Hospitals | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |
| Retail Chain Pharmacy | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |
| Retail Independent Pharmacies | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |
| Closed Door (LTC) Pharmacies | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |
| Mail Order Pharmacies | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |
| Physician Offices | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |
| Wholesalers | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |
| Retail Chain Distribution Centers | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |
| Government- DOD/VA | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |
| Pain Clinics | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |
| Bariatric Clinics | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |
| Veterinary Clinics | Yes ☐ No ☐ | # of accounts Click here to enter text. | # receiving controlled substances Click here to enter text. |

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Veterinary Wholesaler Yes ☐ No ☐ # of accounts Click here to enter text. # receiving controlled substances Click here to enter text.

## V. SOM AND ANTI-DIVERSION PROGRAM

26. Company has a Suspicious Order Monitoring Program which complies with 21CFR 1301.74(b) for controlled substances? Yes ☐ No ☐
27. Company has a Suspicious Order Monitoring Program which complies with 21 U.S.C. 830(b) for listed chemicals? Yes ☐ No ☐ N/A ☐
28. Company complies with the controlled substances and chemical laws of every state in which it is distributing controlled substances and/or listed chemicals? Yes ☐ No ☐
29. Please provide a copy of your Suspicious Order Monitoring Program SOP or Summary of Program.
30. Please provide contact information for SOM department point of contact.
    a. Name: Click here to enter text.
    b. Phone: Click here to enter text.
    c. Email: Click here to enter text.

31. Please provide contact information regarding held orders needing additional information
    a. Name: Click here to enter text.
    b. Phone: Click here to enter text.
    c. Email: Click here to enter text.



_____
Signature

_____
Printed Name

_____
Date

Qualitest
130 Vintage Drive
Huntsville, AL 35811
256.859.4011

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| Qualitest an endo health solution | Title: **RETAIL PHARMACY CONTROLLED SUBSTANCE QUESTIONNAIRE** | |
|---|---|---|
| Form No.: **DEA 53015.02** | Version: **01** | Effective: **07/15/2014** |
| Department: **DEA** | | |

Name of Field Sales Representative: Click here to enter text.

Name of Inside Sales Representative: Click here to enter text.

Qualitest Account number: Click here to enter text. number of years active with QT: Click here to enter text.

This questionnaire is to be completed by the Owner/Manager or Authorized Pharmacist in Charge

## Pharmacy Information

1. Name: Click here to enter text.
   DBA,if any: Click here to enter text.
2. Address: Click here to enter text.
3. Phone Number: Click here to enter text. Fax Number: Click here to enter text.
4. Email Address: Click here to enter text.
5. Has the pharmacy ever operated under a different name?
   Yes ☐ No ☐ if yes, provide the Name: Click here to enter text.
6. Hours of operation: Click here to enter text.
7. Name of pharmacist in charge (PIC): Click here to enter text. License #: Click here to enter text.
8. DEA license number: Click here to enter text.
9. State License number: Click here to enter text.
10. Is this pharmacy affiliated with any other pharmacy? Yes ☐ No ☐ ( if yes, provide the following)
    Name: Click here to enter text.
    Address: Click here to enter text.
    Phone Number: Click here to enter text. Fax Number: Click here to enter text.
    .
11. Has the Pharmacy ever had a DEA registration suspended or revoked?
    Yes ☐ No ☐ If so, give details (when, why, etc.) Click here to enter text.
12. Is the pharmacy a member of any professional associations (NABP, NCPA, APHA, etc.)
    Yes ☐ No ☐ if yes, provide name(s): Click here to enter text.

| Qualitest an endo health solution | Title: **RETAIL PHARMACY CONTROLLED SUBSTANCE QUESTIONNAIRE** | |
|---|---|---|
| Form No.: **DEA 53015.02** | Version: **01** | Effective: **07/15/2014** |
| Department: **DEA** | | |

13. Does the pharmacy have any other certifications? (VIPPS-Verified Internet Pharmacy Practice Sites™, etc.) Yes ☐ No ☐ if yes, give specifics: Click here to enter text.
14. Does the pharmacy have any other licensure/registration (wholesale, re-packager, etc.)?
    Yes ☐ No ☐ if yes, provide copies of license.
15. Is the pharmacy a specialty pharmacy?
    Yes ☐ No ☐ if yes what type: Click here to enter text.
16. Check the following manners of obtaining prescriptions and provide the percentage of each below:

| | | |
|---|---|---|
| Walk-in | Yes ☐ No ☐ | Click here to enter text.% |
| Phone | Yes ☐ No ☐ | Click here to enter text.% |
| Fax | Yes ☐ No ☐ | Click here to enter text.% |
| Internet | Yes ☐ No ☐ | Click here to enter text.% |

17. Which state(s) does the pharmacy ship into (if any)? Click here to enter text.
    (attach copies of all licenses for states to which the pharmacy distributes)
18. Please explain your system of verifying the authenticity of a prescription. (as per: 21CFR 1306)
    Click here to enter text.
19. Average number of prescriptions filled daily Click here to enter text. monthly Click here to enter text.
    a. What percentages of those prescriptions are for controlled substances? Click here to enter text.
20. Does the pharmacy have a web site?
    Yes ☐ No ☐ if yes, provide address: Click here to enter text.
    **NOTE**: If no, you are required to notify us immediately upon establishing a web site.
21. Is the pharmacy affiliated with a web site?
    Yes ☐ No ☐ if yes, provide web address (es): Click here to enter text.
22. Check the following types of payments the pharmacy receives for products and provide the approximate percentage of total payments:

| | | |
|---|---|---|
| Insurance/Co-Pay | Yes ☐ No ☐ | Click here to enter text.% |
| No Insurance/cash<br>Credit/debit | Yes ☐ No ☐ | Click here to enter text.% |

## Owner Information

| Qualitest an endo health solution | Title: **RETAIL PHARMACY CONTROLLED SUBSTANCE QUESTIONNAIRE** | |
|---|---|---|
| Form No.: **DEA 53015.02** | Version: **01** | Effective: **07/15/2014** |
| Department: **DEA** | | |

1. Name: Click here to enter text.
2. Business Address: Click here to enter text.
3. Phone number: Click here to enter text. Fax number: Click here to enter text. Email: Click here to enter text.
4. Number of years owner has operated pharmacy: Click here to enter text.
5. Is the Owner a licensed pharmacist? Yes ☐ No ☐ License #: Click here to enter text.
6. Ownership Type:
   - ❖ Sole Proprietor: Click here to enter text.
   - ❖ Corporation: Click here to enter text.
     State of Incorporation: Click here to enter text. Incorporation Date: Click here to enter a date.
     Principals / Officer(s): Click here to enter text.
     Phone Number: Click here to enter text. fax: Click here to enter text. email: Click here to enter text.
   - ❖ LLC: Click here to enter text.
   - ❖ Partnership: Click here to enter text.
   - ❖ Other: Click here to enter text.
     Please explain: Click here to enter text.
7. Has the Owner/Officer ever had a DEA registration suspended or revoked?
   Yes ☐ No ☐ If so, give details (when, why, etc.) Click here to enter text.



## Wholesaler Information:

1. Primary Wholesaler: Click here to enter text. How long Click here to enter text.
2. Secondary Wholesaler: Click here to enter text. How long Click here to enter text.
3. Other: Click here to enter text. How long Click here to enter text.
4. Other: Click here to enter text. How long Click here to enter text.
5. Has any supplier reduced the amount of controlled substance products your pharmacy may purchase? Yes ☐ No ☐
   Name of Supplier: Click here to enter text.
   Reason for Limit: Click here to enter text.
6. Please provide a list of companies from which you intend to purchase controlled drugs:
   Click here to enter text.

## Please provide the following documentation:

| Qualitest an endo health solution | Title: **RETAIL PHARMACY CONTROLLED SUBSTANCE QUESTIONNAIRE** | **E0607.17** |
|---|---|---|
| Form No.: **DEA 53015.02** | Version: **01** | Effective: **07/15/2014** |
| Department: **DEA** | | |

1. Photographs of pharmacy building:
   a. 2 of inside, including counter area
   b. 2 of outside, front and back of pharmacy

2. 12 month full dispensing history(Excluding GA accounts)

   - **Name of drug and dosage units only.**
   - **Please include total dosage unit count.**
   - **Please do not include patient information.**

   ****** Dispensing history is required to purchase controlled substances from Qualitest Pharmaceuticals. *******

3. Copy of State, DEA, and Pharmacist in Charge licenses

4. Pharmacy Certification(s) if applicable

I, as the Owner or Authorized Corporate Representative, declare that I have completed this Retail Pharmacy Questionnaire to the best of my knowledge and believe the information provided is true, correct and complete.

_____
Signature

_____
Name (print)

_____
Title

_____
Phone Number

_____
Date

| Qualitest an endo health solution | Title: **MAIL ORDER PHARMACY CONTROLLED SUBSTANCE QUESTIONNAIRE** | **E0607.18** |
|---|---|---|
| Form No.: **DEA-53015.03** | Version: **00** | Effective: **07/15/2014** |
| Department: **DEA** | | |

This questionnaire is to be completed for each DEA registered facility

## Corporate Information

1. Name: Click here to enter text.
2. Business Address: Click here to enter text.
3. Phone number: Click here to enter text. Fax number: Click here to enter text. Email: Click here to enter text.
4. Ownership Type:
   - ❖ Sole Proprietor: Click here to enter text.
   - ❖ Corporation: Click here to enter text.
   - ❖ LLC: Click here to enter text.
   - ❖ Partnership: Click here to enter text.
   - ❖ Other: Click here to enter text.
   - Please explain: Click here to enter text.

## Pharmacy Information

1. Name: Click here to enter text.
   DBA,if any Click here to enter text.
2. Address: Click here to enter text.
3. Phone Number: Click here to enter text. Fax Number: Click here to enter text.
4. Name of pharmacist in charge (PIC): Click here to enter text. License #: Click here to enter text.
5. DEA license number: Click here to enter text.
6. State License number: Click here to enter text.
7. Has the Pharmacy ever had a DEA registration suspended or revoked?
   Yes ☐ No ☐ If so, give details (when, why, etc.) Click here to enter text.
8. Does the pharmacy have any other certifications? (VIPPS-Verified Internet Pharmacy Practice Sites™, etc.) Yes ☐ No ☐ if yes, give specifics: Click here to enter text.

| Qualitest an endo health solution | Title: **MAIL ORDER PHARMACY CONTROLLED SUBSTANCE QUESTIONNAIRE** | |
|---|---|---|
| Form No.: **DEA-53015.03** | Version: **00** | Effective: **07/15/2014** |
| Department: **DEA** | | |

9. Does the pharmacy have any other licensure/registration (wholesale, re-packager, etc.)?
   Yes ☐ No ☐ if yes, provide copies of license.

10. Please explain your system of verifying the authenticity of a prescription. (as per: 21CFR 1306)
    Click here to enter text.

11. Average number of prescriptions filled monthly Click here to enter text.
    a. What percentages of those prescriptions are for controlled substances? Click here to enter text.

12. Check the following types of payments the pharmacy receives for products and provide the approximate percentage of total payments:

| | | |
|---|---|---|
| Insurance | Yes ☐ No ☐ | Click here to enter text.% |
| No Insurance | Yes ☐ No ☐ | Click here to enter text.% |

13. Please provide a list of companies from which you intend to purchase controlled drugs:

| | |
|---|---|
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |

14. Please provide contact information for SOM department point of contact.
    a. Name: Click here to enter text.
    b. Phone: Click here to enter text.
    c. Email: Click here to enter text.

15. Please provide contact information regarding held orders needing additional information
    a. Name: Click here to enter text.
    b. Phone: Click here to enter text.
    c. Email: Click here to enter text.

| Qualitest an endo health solution | Title: **MAIL ORDER PHARMACY CONTROLLED SUBSTANCE QUESTIONNAIRE** | **E0607.20** |
|---|---|---|
| Form No.: **DEA-53015.03** | Version: **00** | Effective: **07/15/2014** |
| Department: **DEA** | | |

OTHER COMMENTS: Click here to enter text.

I, as the Owner or Authorized Corporate Representative, declare that I have completed this Mail Order Pharmacy Questionnaire to the best of my knowledge and believe the information provided is true, correct and complete.

_____
Signature

_____
Name (print)

_____
Title

_____
Phone Number

_____
Date

| Qualitest an endo health solution | Title: MAIL ORDER PHARMACY ANNUAL REVIEW | E0607.21 |
|---|---|---|
| Form No.: **DEA-53015.04** | Version: **00** | Effective: **07/15/2014** |
| Department: **DEA** | | |

******must be completed for each DEA registered location******

Account Name/DBA: Click here to enter text. City/St: Click here to enter text.

DEA#: Click here to enter text. State License #: Click here to enter text.

1. Have any disciplinary actions been taken against the facility in the past year? Yes ☐ No ☐
2. Has there been a change in ownership in the past year? Yes ☐ No ☐
3. Please provide contact information for the SOM department point of contact.
   a. Name: Click here to enter text.
   b. Phone: Click here to enter text.
   c. Email: Click here to enter text.
4. Please provide contact information in regards to held orders needing additional information
   a. Name: Click here to enter text.
   b. Phone: Click here to enter text.
   c. Email: Click here to enter text.
5. Average number of prescriptions filled monthly: Click here to enter text.
   a. What percentages of those prescriptions are for controlled substances? Click here to enter text.

Printed name/Title _____

Signature _____ Date _____

Discard any unused electronic printouts 2 calendar days from their date of printing 4/16/2015

| Qualitest an endo health solution | Title: **WHOLESALE/DISTRIBUTOR/CHAIN ANNUAL REVIEW** | |
|---|---|---|
| Form No.: **DEA-53015.05** | Version: **00** | Effective: **07/15/2014** |
| Department: **DEA** | | |

Account Name/DBA: Click here to enter text. City/St: Click here to enter text.

DEA#: Click here to enter text. State License #: Click here to enter text.

1. Have any disciplinary actions been taken against the facility in the past year?
   Yes ☐ No ☐ if yes please explain: Click here to enter text.
2. Has there been a change in ownership in the past year? Yes ☐ No ☐
3. Please provide contact information for the SOM department point of contact.
   a. Name: Click here to enter text.
   b. Phone: Click here to enter text.
   c. Email: Click here to enter text.
4. Please provide contact information in regards to held orders needing additional information
   a. Name: Click here to enter text.
   b. Phone: Click here to enter text.
   c. Email: Click here to enter text.
5. Please update the type and number of accounts that are supplied by your facility:

| | | |
|---|---|---|
| Hospitals<br>Click here to enter text. | Yes ☐ No ☐ # of accounts Click here to enter text. | # receiving controls |
| Retail Chain Pharmacy<br>Click here to enter text. | Yes ☐ No ☐ # of accounts Click here to enter text. | # receiving controls |
| Retail Independent Pharmacies<br>Click here to enter text. | Yes ☐ No ☐ # of accounts Click here to enter text. | # receiving controls |
| Closed Door (LTC) Pharmacies<br>Click here to enter text. | Yes ☐ No ☐ # of accounts Click here to enter text. | # receiving controls |
| Mail Order Pharmacies<br>Click here to enter text. | Yes ☐ No ☐ # of accounts Click here to enter text. | # receiving controls |
| Physician Offices<br>Click here to enter text. | Yes ☐ No ☐ # of accounts Click here to enter text. | # receiving controls |
| Wholesalers<br>Click here to enter text. | Yes ☐ No ☐ # of accounts Click here to enter text. | # receiving controls |
| Retail Chain Distribution Centers<br>Click here to enter text. | Yes ☐ No ☐ # of accounts Click here to enter text. | # receiving controls |
| Government- DOD/VA<br>Click here to enter text. | Yes ☐ No ☐ # of accounts Click here to enter text. | # receiving controls |
| Pain Clinics<br>Click here to enter text. | Yes ☐ No ☐ # of accounts Click here to enter text. | # receiving controls |
| Bariatric Clinics<br>Click here to enter text. | Yes ☐ No ☐ # of accounts Click here to enter text. | # receiving controls |



Discard any unused electronic printouts 2 calendar days from their date of printing 4/16/2015

Veterinary Clinics Yes ☐ No ☐ # of accounts Click here to enter text. # receiving controls
Click here to enter text.

Veterinary Wholesaler Yes ☐ No ☐ # of accounts Click here to enter text. # receiving controls
Click here to enter text.

Printed name/Title _____

Signature _____ Date _____



Discard any unused electronic printouts 2 calendar days from their date of printing 4/16/2015

# STANDARD OPERATING PROCEDURE

| Qualitest an endo health solution | Title: **NEW ACCOUNT APPROVAL & EXISTING ACCOUNT REVIEW** | |
|---|---|---|
| No.: **DEA-53015** | Version: **00** | Effective: **12/23/2013** |
| Department: **DEA COMPLIANCE** | | |

PURPOSE: This SOP outlines the review and approval process for new Controlled Substance accounts as well as annual or for cause reviews of existing Controlled Substance accounts, including those customers requesting to order Controlled Substances for the first time.

SCOPE: This SOP applies to all customers in all trade classes that purchase Controlled Substances and/or List 1 Chemicals.

DEFINITIONS:

| | |
|---|---|
| Pharmaceutical Diversion | Excessive purchases of Controlled Substances or List1 chemicals with intent of illicit use or distribution. |
| Controlled Substances | A drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V in Title 21 U.S.C. |
| List 1 Chemicals | A chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of Title 21 U.S.C. and is important to the manufacture of the controlled substance. |

RESPONSIBILITY: The Qualitest Sales team has the primary responsibility of collecting all of the required documents and licenses and submitting them to the SOM Team.
The SOM Team has the responsibility of reviewing all required documents and licenses. The Director, DEA Compliance or Manager, Customer Due Diligence & SOM have the responsibility for final approval of customers for shipment of Controlled Substances after determining risk of diversion.

SAFETY: N/A

REFERENCES: N/A

ATTACHMENTS: Retail Customer Questionnaire
Wholesale / Chain Warehouse Questionnaire

| Qualitest an endo health solution | Title: **NEW ACCOUNT APPROVAL & EXISTING ACCOUNT REVIEW** | |
|---|---|---|
| No.: **DEA-53015** | Version: **00** | Effective: **12/23/2013** |
| Department: **DEA COMPLIANCE** | | |

PROCEDURE:

I. General

A. Prior to the initial sale of Controlled Substances and List 1 Chemicals, the SOM Team conducts a thorough review and research of the customer including ownership. If the research concludes that the potential customer poses an unreasonable risk for diversion of Controlled Substances and/or List 1 chemicals, the customer will be blocked from ordering Controlled Substances and/or List 1 Chemicals.

II. Know Your Customer

A. The Sales team sends the appropriate customer Questionnaire to the potential customer [redacted] The completed Questionnaire and supporting documentation is sent to the SOM group mailbox.

B. The SOM team reviews and validates the information provided by the customer. This information includes but is not limited to:

1. Name, address, phone and website
2. State and DEA licenses are verified and any disciplinary action is researched
3. [redacted]
4. [redacted]
5. Affidavit of compliance with regulations relating to Controlled Substances

C. If the new customer is a [redacted] the following additional research is conducted to help determine risk of diversion of Controlled Substances and to assist in establishing proper boundaries that minimize company risk while serving the customers legitimate need. Listed below are some of the criteria that would be reviewed:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]

D. If the new customer is a [redacted] the following additional research is conducted after section "b" is completed:

| Qualitest an endo health solution | Title: **NEW ACCOUNT APPROVAL & EXISTING ACCOUNT REVIEW** | |
|---|---|---|
| No.: **DEA-53015** | Version: **00** | Effective: **12/23/2013** |
| Department: **DEA COMPLIANCE** | | |

[redacted]

E. If red flags are identified during review, the SOM team may request additional information related to the red flag from the potential customer.

F. The final decision to approve or reject the account with regard to the ability to order Controlled Substances or List 1 Chemicals is made on whether the customer poses an unreasonable risk for the diversion of Controlled Substances.

G. All information related to the final decision must be documented and saved pursuant to the Record Retention Policy.

---

END SOP

REVISION HISTORY:
REV00 – New SOP

# STANDARD OPERATING PROCEDURE

| Qualitest an endo health solution | Title: **CAGE / VAULT SUSPICIOUS ORDER MONITORING** | |
|---|---|---|
| No.: **DEA-53012** | Version: **00** | Effective: **12/23/2013** |
| Department: **DEA COMPLIANCE** | | |

PURPOSE: To provide requirements for monitoring and reporting by cage/vault distribution center employees and CIII-V order entry employees customer orders that are of unusual size, frequency or deviates from normal pattern.

SCOPE: This procedure applies to Qualitest cage / vault distribution center employees as well as employees responsible for CIII-V order entry and 222 form entry.

DEFINITIONS:

| | |
|---|---|
| Order of Interest | An order that appears based on the skill, customer knowledge and experience of the Qualitest employee to significantly deviate from the customer's normal ordering pattern. |
| Controlled Substance | A drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V in Title 21 U.S.C. |
| List 1 Chemical | A chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of Title 21 U.S.C. and is important to the manufacture of the controlled substance. |
| Suspicious Order | An order for a controlled substance or List 1 chemical which is of an unusual size, frequency, and/or deviates substantially from a normal pattern. |

RESPONSIBILITY: Cage / vault distribution center employees, CIII-V order entry and 222 entry employees are responsible for the execution of this SOP.

SAFETY: N/A

REFERENCES: N/A

ATTACHMENTS: N/A

| Qualitest an endo health solution | Title: **CAGE / VAULT SUSPICIOUS ORDER MONITORING** | |
|---|---|---|
| No.: **DEA-53012** | Version: **00** | Effective: **12/23/2013** |
| Department: **DEA COMPLIANCE** | | |

PROCEDURE:

I. Controlled Substance or List 1 Chemical Orders of Interest

A. Controlled Substance or List 1 Chemical orders of interest may consist of one or more of the following:

1. [redacted]
2.
3.
4. Others factors deemed unusual from employee's knowledge of customer

B. If during the course of entering or picking orders for Controlled Substances or List 1 chemicals the employee identifies an order of interest, the employee notifies his /her supervisor. The supervisor alerts the SOM team for further review.

C. The SOM team reviews the order and follows the Identifying, Blocking & Reporting SOP.

D. If the order is deemed suspicious it is reported to the DEA by the Director, DEA Compliance or designee.

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END SOP

REVISION HISTORY:
REV00 – NEW SOP